MAY - 3 2000

Le groupe précident

510(k) Summary

Clini-dent

K 000140

Submitter:	The Precident Group 845 Beauregard, Suite 409 Ste-Foy, Quebec, Canada G1V 4P4 Telephone: 1-800-752-3368 Fax: 418-659-7394 Contact person: Yvan Bouret
Regulatory Contact:	**Wendy Bedale, Ph.D.** Regulatory Scientist Cato Research Ltd. 200 Westpark Corporate Center 4364 South Alston Avenue Durham, North Carolina 27713-2280 Telephone: 919-361-2286 Fax: 919-361-2290
Date of preparation:	22 December, 1999
Device Name:	Proprietary Name: Clini-dent™
Common Name:	Dental eraser or dental stain remover
Classification Name:	Manual toothbrush
Regulatory Classification:	
Class:	I
Medical Specialty Panel:	Dental
Product Code:	76EFW

Device to Which Substantial Equivalence is Claimed:

Device Name:	Dental Stain Remover by Concept Inc.
510(k) Number:	K761352

Device Description:
The Clini-dent is a dental eraser or dental stain remover. It has an operating handle designed to be held with one hand. One end of the handle is angled and terminates in a working end-piece forming a housing that has its opening at the extremity of this end-piece. The housing is intended to receive part of the body of a working tool, removably fixed on the end-piece by being partially engaged within the housing. The tool consists of an eraser formed by a body of molded synthetic resin within which are incorporated abrasive and polishing elements.

Intended Use:
The Clini-dent is a dental eraser and is indicated for the removal of stains and plaque from the surface of the tooth. It is designed to be used by anyone, with no special training required. The Clini-dent is used by rubbing the tooth surfaces with the blue end of the eraser. After use, the mouth should be rinsed thoroughly, and the dental eraser should be cleaned under running water. The product should be kept in a clean, cool, and dry area and should not be exposed directly to the sun. Frequent use will not damage the tooth surface. Application

over a longer period of time may be necessary to remove persistent stains. The use of the Clini-dent is not meant to replace brushing of teeth and regular visits to the dentist.

Substantial Equivalence:
The Clini-dent is similar to the Dental Stain Remover by Concept Inc. because of the following:

- both are designed to remove stains from the surface of the tooth;
- both devices use the principle of abrasion; and
- they are both for home use.

The main differences are that the Clini-dent can be used daily; whereas, Concept Inc.'s device can be used only as necessary to remove stains. The Clini-dent is a simple device that is manually operated, but Concept Inc.'s device has a motor that is battery operated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 9 = 2000

The President Group
C/O Kevin Barber, Ph.D.
Cato Research Limited
200 Westpark Corporate Center
4364 South Alston Avenue
Durham, North Carolina 27713-2280

Re: K000140
Trade Name: Clini-dent™
Regulatory Class: Unclassified
Product Code: MAU
Dated: April 24, 2000
Received: April 25, 2000

Dear Dr. Barber:

This letter corrects our substantially equivalent letter of May 3, 2000, regarding the contact person and the obligation you might have under sections 531 through 542 of the Act.

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Applicant: Yvan Bouret, President, The Precident Group

510(k) Number (if known): K000140
Device Name: Clini-dent™
Indications For Use:

The Clini-dent™ is a dental eraser and is indicated for the removal of stains and plaque from the surface of the tooth. It is designed to be used by anyone, with no special training required. The Clini-dent™ is used by rubbing the tooth surfaces with the blue end of the eraser. After use, the mouth should be rinsed thoroughly, and the dental eraser should be cleaned under running water. The product should be kept in a clean, cool, and dry area and should not be exposed directly to the sun. Frequent use will not damage the tooth surface. Application over a longer period of time may be necessary to remove persistent stains. The use of the Clini-dent™ is not meant to replace brushing of teeth and regular visits to the dentist.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-counter ✓
Per 21 CFR 801.109
(Optional Format 1-2-96)

S.L. Shine, DMD, MPA for MSR
(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K000140